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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/096,589	06/12/1998	ROBERT J. SCHNEIDER	5914-65	1985

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EXAMINER
PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/27/2002 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/096,589	Schneider et al.
Examiner	**Art Unit**
Rebecca Prouty	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 9, 2001

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 47-50 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 47-50 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Claims 1-46 have been canceled. Newly presented claims 47-50 are at issue and are present for examination.

Applicants' arguments filed on 11-9-01, paper No. 12, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 47-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to methods of inhibiting HBV infection or replication by administering a compound that inhibits enhanced activity of Src kinase which results from the presence of HBx. The specification fails to describe in any fashion the physical and/or chemical properties or any identifying characteristics or properties other than the functionality of inhibiting enhanced activity of Src kinase resulting from the presence of HBx of the claimed class of substances and fails to identify even a single representative species of such compounds. Moreover, the specification fails to describe how the presence of HBx results in the activation of Src

kinase such that the ordinary skilled artisan would have guidance regarding the types of compounds which should be investigated. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicants argue that the specification provides a description of the unifying characteristic (i.e., ability to reduce the activation of Src kinase) of the genus of compounds useful in the instant methods and that there is no requirement that they detail each and every compound within the claimed genus. This is not persuasive because the rejection never required the specification to detail each and every compound within the claimed genus but instead to provide a sufficient description such that members of the genus can be recognized. A sufficient description of a genus requires a precise definition, such as by structure, formula, chemical name or physical properties of members of the genus such that one skilled in the art can visualize or recognize the identity of the members of the genus.

Applicants further argue that the identification of members of the genus using the assays described in sections 5.5 and 5.5.1

of the specification would not require undue experimentation in view of the screening assays taught in the specification and the availability of high throughput screening methods in the art. This is not persuasive because the instant rejection is not for lack of enablement but for lack of written description. Description and enablement are separate issues under 35 U.S.C. 112, first paragraph.

Claims 48 and 50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of inhibiting HBV replication with compounds which reduce Src kinase activation resulting from the presence of HBx, does not reasonably provide enablement for methods of inhibiting HBV replication with any compound which reduces Src kinase activation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims broadly recite the use of **any** substance reduces Src kinase activation to inhibit HBV infection or replication. The specification fails to describe in any fashion the physical and/or chemical properties or any identifying characteristics or properties other than the functionality of reducing Src kinase

activation of the claimed class of substances and fails to identify even a single such compound. Src kinases are known to be activated by a variety of pathways within the cell but the specification fails to teach that HBx activates these kinases by any of these known signal transduction pathways nor teaches a new pathway for the activation of Src kinases by HBx (or other HBV proteins). As such administering compounds which inhibit any of the known pathways of Src kinase activation would likely be ineffective to inhibit HBV replication as HBx appears to activate Src kinases independently of these pathways. While the prior art teaches a number of upstream activators of Src kinases (growth factor receptors, the ligands which activate these receptors, and receptor protein tyrosine phosphatase α) none of these has been shown to interact with any HBV protein, including HBX in particular. Without some showing how HBX (or another HBV protein) activates Src kinases *in vivo* one of ordinary skill in the art would have no reasonable expectation that inhibiting one or more upstream activators of Src kinases would have any effect on HBV infection and/or replication. Furthermore, the screening methods recited in Claim 50 (which test the effect of a compound on the activation of Src kinase) would not lead one of ordinary skill in the art to compounds which inhibit HBV unless the

compound inhibits the same activation pathway that is used by HBV. While the specification suggests that HBX mediated induction of Src kinase is necessary for initiating and/or maintaining HBV infection, neither the specification nor the art provides any teaching of the mechanism by which HBX activates Src and none of the known activities of the HBX protein suggest any particular method of Src activation. As such practice of the claimed methods would require undue experimentation to find and make compounds with the claimed activities.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Moriya et al.

Moriya et al. teach the inhibition of HBV by administration of HBx antisense oligonucleotides. While Moriya et al. do not show that these oligonucleotides inhibit activation of Src kinase, this is an inherent effect of the method of Moriya et al. as the oligonucleotides of Moriya inhibit HBx expression such that these is no HBx present to activate Src kinase. While the properties of the oligonucleotides of Moriya et al. were not

identified by the process recited in claims 49-50, the properties of a compound are inherent within the structure of the compound. Anticipation is not negated by a lack of disclosure of inherent properties of a prior art compound. Furthermore, the means of identifying the properties of a compound fails to in any way alter the compound itself and therefore, fails in any way to further define the compound of the recited methods as in some cases is seen in product-by-process claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty
Primary Examiner
Art Unit 1652